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12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA
14 SAN FRANCISCO DIVISION

16 GENERAL ATOMICS, DIAZYME
17 LABORATORIES DIVISION, a California
corporation,

18 Plaintiff,

19 v.
20 AXIS-SHIELD ASA, a Norway corporation,
21 Defendant.

Case No. 3:05-cv-04074 SI

**GENERAL ATOMICS' AMENDED
COMPLAINT FOR
DECLARATORY RELIEF**

DEMAND FOR JURY TRIAL

23
24 Plaintiff General Atomics, Diazyme Laboratories Division ("GENERAL ATOMICS") by
25 its undersigned attorneys, alleges as follows:

26 **PARTIES**

27 1. Plaintiff GENERAL ATOMICS is a corporation existing under the laws of the
28 State of California, and having its principal place of business at 3550 General Atomics Court, San

Diego, California 92121. GENERAL ATOMICS, Diazyme Laboratories Division is a manufacturer of homocysteine assays which are sold worldwide.

3 2. GENERAL ATOMICS is informed and believes, and on that basis alleges, that
4 defendant AXIS-SHIELD ASA (“AXIS-SHIELD”) is a corporation organized and existing under
5 the laws of the Country of Norway and has its principal place of business in Oslo, Norway.
6 AXIS-SHIELD is a publicly-traded, global company that sells products that measure
7 homocysteine in human blood samples, among other things, in the United States in competition
8 with GENERAL ATOMICS. GENERAL ATOMICS is informed and believes, and on that basis
9 alleges, that AXIS-SHIELD does a substantial amount of business in the United States and in the
10 Northern District of California. GENERAL ATOMICS is informed and believes, and on that
11 basis alleges, that AXIS-SHIELD’S products are sold to laboratories in the Northern District of
12 California, including but not limited to the U.C.S.F. hospital clinical laboratory.

JURISDICTION

14 3. This is an action for declaratory relief pursuant to Rule 57 of the Federal Rules of
15 Civil Procedure and 28 U.S.C. §§ 2201 and 2202 for the purpose of determining a question of
16 actual controversy between the parties as hereinafter more fully appears.

17 4. This court has jurisdiction over the action pursuant to 28 U.S.C. § 1338(a) (action
18 arising under an Act of Congress relating to patents) and 28 U.S.C. § 1331 (federal question).

VENUE

20 5. Venue is proper in this judicial district under 28 U.S.C. § 1331(b)-(c) in that
21 GENERAL ATOMICS is informed and believes, and on that basis alleges, that AXIS-SHIELD is
22 subject to personal jurisdiction within the State of California and this judicial district by virtue of,
23 *inter alia*, its regular and systematic business contacts with this judicial district, and its threat
24 letters and licensing demands to GENERAL ATOMICS in California. AXIS-SHIELD
25 accordingly resides within this judicial district for venue purposes.

INTRADISTRICT ASSIGNMENT

27 6. Assignment to the San Francisco Division is proper because the action arises in the
28 County of San Francisco.

FACTUAL BACKGROUND

2 7. GENERAL ATOMICS has obtained FDA approval for sale in the United States of
3 its enzymatic homocysteine assays to detect the level of homocysteine present in human samples.
4 General Atomics currently manufactures, sells, and intends to sell throughout the United States its
5 enzymatic homocysteine assays.

6 8. This is in part an action for a declaratory judgment that GENERAL ATOMICS'
7 homocysteine assay does not infringe U.S. Patent No. 5,631,127 ("the '127 patent"), U.S. Patent
8 No. 5,958,717 ("the '717 patent"), U.S. Patent No. 5,827,645 ("the '645 patent"), and U.S. Patent
9 No. 6,063,581 ("the '581 patent"). Copies of the '127 patent, '717 patent, '645 patent, and '581
10 patent are attached to this Complaint as Exhibits A-D, respectively. The '127 patent, '717 patent,
11 '645 patent, and '581 patent generally purport to disclose and claim technology to detect the level
12 of homocysteine in blood, plasma, or urine.

13 9. This is also an action for a declaratory judgment that the ‘127 patent, ‘717 patent,
14 ‘645 patent, and ‘581 patent are invalid under 35 U.S.C. §§ 102, 103 and one or more paragraphs
15 of 35 U.S.C. § 112, and that the ‘127 patent and the ‘717 patent are invalid under the doctrine of
16 obviousness type double patenting.

17 10. AXIS-SHIELD purports to be the owner by assignment of the ‘127 patent,
18 ‘717 patent, ‘645 patent, and ‘581 patent. Moreover, AXIS-SHIELD is identified at the assignee
19 of the ‘127 patent, ‘717 patent, ‘645 patent, and ‘581 patent on the United States Patent and
20 Trademark Patent Assignment Record.

21 11. GENERAL ATOMICS' enzymatic homocysteine assay has not and does not
22 infringe the '127 patent, '717 patent, '645 patent, or '581 patent.

REASONABLE APPREHENSION OF SUIT

24 12. AXIS-SHIELD has explicitly threatened GENERAL ATOMICS with suit on its
25 homocysteine assay patents, which include the ‘127 patent, ‘717 patent, ‘645 patent, and ‘581
26 patent. For example, on September 27, 2005, Erling Sundrehagen, M.D., M.Sc. Ph.D., AXIS-
27 SHIELD’s Chief Scientific Officer, and the sole named ‘127 patent, ‘717 patent, ‘645 patent, and
28 ‘581 patent inventor, threatened GENERAL ATOMICS in writing in an e-mail to GENERAL

1 ATOMICS, Diazyme Laboratories Division's Managing Director Chong Yuan, Ph.D. stating:
 2 "After thorough consideration, we have arrived at the conclusion that also your new
 3 homocysteine technology infringes Axis-Shield's homocysteine patents. (I can send a more
 4 detailed explanation in a separate mail). We understand that Diazyme holds a different opinion.
 5 We cannot, however, see collaboration between our companies going forward without resolving
 6 this difference in opinion. On the other hand we are confident that Diazyme immediately will
 7 have a much bigger and more growing homocysteine business with fully licensed products."
 8 AXIS-SHIELD's accusation of patent infringement was followed by two licensing proposals.

9 13. Again, on October 5, 2005, Dr. Sundrehagen wrote in an e-mail to Dr. Yuan "I
 10 strongly suggest we start discussing terms, otherwise this will only roll on to a legal dispute."
 11 Dr. Sundrehagen attached a note to this communication stating "We will also point to the
 12 existence of several other Axis-Shield US patents relevant to the Diazyme product. If needed, we
 13 can in due time provide more detailed analyses of US patent 5958717 and the other relevant
 14 patents." (typographical errors in original).

15 14. Thus, GENERAL ATOMICS is informed and believes, and on that basis alleges,
 16 that AXIS-SHIELD contends that the '127 patent, '717 patent, '645 patent, and '581 patent are
 17 purportedly valid, enforceable and infringed by GENERAL ATOMICS' enzymatic homocysteine
 18 assay.

19 15. GENERAL ATOMICS is further informed and believes, and on that basis alleges,
 20 that AXIS-SHIELD actively polices its issued patents. For example, on October 9, 2001, AXIS-
 21 SHIELD filed a Complaint for patent infringement of the '127 and '717 patents against
 22 GENERAL ATOMICS in the Southern District of California based on other GENERAL
 23 ATOMICS homocysteine assay products. This Complaint, Case No. 01 CV 1836 J (RBB), was
 24 voluntarily dismissed on March 22, 2002. Moreover, on August 1, 2003, Axis-Shield filed a
 25 Complaint alleging infringement of the '127 patent and '717 patent against Carolina Liquid
 26 Chemistries Corporation and Catch Incorporated in the Central District of California (Case No.
 27 8:03-cv-01210-DOC-MLG).

28

1 16. The foregoing facts and circumstances give rise to a reasonable apprehension of
2 suit on the part of Plaintiff GENERAL ATOMICS. There is now existing an actual, justiciable,
3 controversy between the parties with respect to the validity, enforceability, and infringement of
4 the ‘127 patent, ‘717 patent, ‘645 patent, and ‘581 patent. Accordingly, GENERAL ATOMICS
5 is entitled to have a declaration of its rights and further relief as requested herein.

INEQUITABLE CONDUCT

7 17. This is also an action for a declaratory judgment that the '127 patent, '717 patent,
8 '645 patent, and '581 patent are void and unenforceable for inequitable conduct.

9 18. Trewyn and Kerr, *J. Biochem. Biophys. Methods*, 4(5-6):299-307 (1981)
10 (“Trewyn”) was published in 1981, and is therefore prior art to the ‘127 patent, ‘717 patent, ‘645
11 patent, and ‘581 patent under, *inter alia*, 35 U.S.C. § 102(b).

12 19. Trewyn anticipates and/or renders obvious at least claims 1-5, 7-8, 11-12 and 18 of
13 the ‘127 patent, and would be considered material by a reasonable examiner in deciding whether
14 to allow these claims. Upon information and belief, the law firm Bacon & Thomas and/or
15 attorney Richard E. Fichter (Reg. No. 26,382) knew of Trewyn and its materiality because Bacon
16 & Thomas and/or Richard E. Fichter had previously submitted Trewyn to the Patent Office in
17 connection with the U.S. Patent Application Serial No. 07/833,118 (‘118 Application) (See May
18 20, 1992 Information Disclosure Statement in connection with the ‘118 Application). The same
19 law firm, Bacon & Thomas, and/or the same attorney, Richard E. Fichter, also prosecuted the
20 ‘127 patent, ‘717 patent, ‘645 patent, and ‘581 patent. In violation of the duty of candor to the
21 Patent Office, Bacon & Thomas and/or Richard E. Fichter failed to disclose Trewyn to the Patent
22 Office in connection with the ‘127 patent and other related patents, such as the ‘717 patent, ‘645
23 patent, and ‘581 patent. Given the materiality of Trewyn and the fact that Bacon & Thomas
24 and/or Richard E. Fichter were in possession of Trewyn and appreciated its materiality, Bacon &
25 Thomas and/or Richard E. Fichter failed to disclose Trewyn to the Patent Office in connection
26 with the ‘127 patent, the ‘717 patent, ‘645 patent, ‘581 patent and other related patents with the
27 intent to mislead the Patent Office.

FIRST CLAIM FOR RELIEF

**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF ‘127 PATENT,
‘717 PATENT, ‘645 PATENT, AND ‘581 PATENT)**

20. GENERAL ATOMICS hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 19 of the Complaint.

21. GENERAL ATOMICS, and its enzymatic homocysteine assays, does not infringe the ‘127 patent, ‘717 patent, ‘645 patent, or ‘581 patent, directly or indirectly, either literally or under the doctrine of equivalents.

22. This judicial declaration is necessary and appropriate at this time in order that GENERAL ATOMICS may ascertain its rights and duties with respect to the '127 patent, '717 patent, '645 patent, and '581 patent.

SECOND CLAIM FOR RELIEF

**(DECLARATORY JUDGMENT OF INVALIDITY OF ‘127 PATENT, ‘717 PATENT,
‘645 PATENT, AND ‘581 PATENT)**

23. GENERAL ATOMICS hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 22 of the Complaint.

24. The ‘127 patent, ‘717 patent, ‘645 patent, and ‘581 patent are invalid under 35 U.S.C. §§ 102, 103, 112, and/or the doctrine of obviousness type double patenting.

25. This judicial declaration is necessary and appropriate at this time in order that GENERAL ATOMICS may ascertain its rights and duties with respect to the '127 patent, '717 patent, '645 patent, and '581 patent.

THIRD CLAIM FOR RELIEF

**(DECLARATORY JUDGMENT OF UNENFORCEABILITY OF ‘127 PATENT,
‘717 PATENT, ‘645 PATENT, AND ‘581 PATENT)**

26. GENERAL ATOMICS hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 25 of the Complaint.

1 27. GENERAL ATOMICS seeks a declaratory judgment pursuant to 28 U.S.C.
2 § 2201(a) that the ‘127 patent, ‘717 patent, ‘645 patent, and ‘581 patent are void and
3 unenforceable for inequitable conduct.

4 28. This judicial declaration is necessary and appropriate at this time in order that
5 GENERAL ATOMICS may ascertain its rights and duties with respect to the '127 patent, '717
6 patent, '645 patent, and '581 patent.

PRAAYER FOR RELIEF

8 WHEREFORE, plaintiff GENERAL ATOMICS prays for a judgment against Defendant
9 AXIS-SHIELD as follows:

- 10 (a) That the Court declare that the enzymatic homocysteine assay sold or distributed
11 by GENERAL ATOMICS does not and would not infringe the ‘127 patent, ‘717
12 patent, ‘645 patent, or ‘581 patent, directly or indirectly, literally or under the
13 doctrine of equivalents, if made, used, offered for sale, or sold in the United States
14 or imported into the United States;

15 (b) That the Court declare that all claims of the ‘127 patent, ‘717 patent, ‘645 patent,
16 and ‘581 patent are invalid;

17 (c) That the Court declare that the ‘127 patent, ‘717 patent, ‘645 patent, and ‘581
18 patent are unenforceable;

19 (d) That the Court deem this case to be “exceptional” within the meaning of 35 U.S.C.
20 § 285 entitling GENERAL ATOMICS to an award of its reasonable attorneys’
21 fees and expenses in this action; and

22 (e) That the Court grant such other and further relief as the Court may deem just and
23 proper.

1
2 **DEMAND FOR JURY TRIAL**
3

4 Pursuant to Federal Rule of Civil Procedure 38(b), GENERAL ATOMICS demands a trial
5 by jury of all issues triable in this action.
6

7
8 Dated: March 1, 2006
9

10 MORRISON & FOERSTER LLP
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12

13 By: /s/ David C. Doyle
14 David C. Doyle
15 Attorneys for Plaintiff
16 GENERAL ATOMICS, DIAZYME
17 LABORATORIES DIVISION
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General Order 45 Attestation

I, Anders T. Aannestad, am the ECF User whose ID and password are being used to file this Joint Case Management Conference Statement. In compliance with General Order 45, X.B., I hereby attest that David C. Doyle has concurred in this filing.

/s/ Anders T. Aannestad
Anders T. Aannestad